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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/784,340	02/16/01	WEI M	CL000763

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EXAMINER	
RAMIREZ, D	
ART UNIT	PAPER NUMBER
1652	5

DATE MAILED: 08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/784,340	WEI ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4, 5, 6, 8, 9, 10, 11, 22, 23 drawn to DNA, vectors, a gene chip, a host cell encoding and expression of a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 536, subclass 23.2.

II. Claims 1, 2, 20, 21, drawn to a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 535, subclass 193.

III. Claim 3, drawn to an antibody that selectively binds a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 530, subclass 387.1.

IV. Claim 7, drawn to a transgenic non-human animal, classified in class 800, subclass 13.

V. Claim 12, drawn to a method of detecting the presence of a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 435, subclass 15.

VI. Claim 13, drawn to a method for detecting a nucleic acid molecule encoding a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 436, subclass 94.

VII. Claims 14-15, drawn to a method for identifying a modulator of a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 436, subclass 63.

VIII. Claim 16, drawn to a method for identifying an agent that binds to a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 435, subclass 7.1.

IX. Claim 17, drawn to a pharmaceutical composition comprising a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 424, subclass 9.1.

X. Claim 18, drawn to a method for treating a disease with an agent that binds a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 424, subclass 9.2.

XI. Claim 19, drawn to a method of identifying a modulator of the expression of a human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Groups I, II, III, and IV each comprise a chemically unrelated structure capable of separate manufacture, use, and effect. The DNA in Group I comprises a nucleic acid sequence, the transgenic non-human animal in Group IV is a multicellular organism whereas the proteins of Group II and III each comprise an unrelated amino acid sequence. The DNA has other uses besides encoding the protein of Group II or being introduced in the transgenic animal of Group IV, such as a hybridization probe or in gene therapy. The transgenic animal of Group IV can

have other uses such as in vivo testing besides manufacturing the protein of Group II. The protein from Group II can be used in materially different methods other than to make the antibody of Group III, such as in therapeutic or diagnostic methods (e.g. in screening). Further, the proteins of Group II and III can be prepared by processes which are materially different from recombinant DNA expression of Group I or expression in the transgenic non-human animal of Group IV, such as by chemical synthesis, or by isolation and purification from natural sources.

The protein of Group II is unrelated to the methods of Groups V, VI, X, and XI as it is neither used nor made by the methods of Groups V, VI, X, and XI.

The protein of Group II, the DNA of Group I, the transgenic non-human animal of Group IV, and the pharmaceutical composition of Group IX are unrelated as they are products that are distinct both physically and functionally, are not required one for the other, and have different uses and effects.

The DNA of Group I is unrelated to the methods of Groups V, VII, VIII, and X as it is neither used nor made by the methods of Groups V, VII, VIII, and X.

The transgenic non-human animal of Group IV is unrelated to the methods of Groups V, VI, VII, VIII, X, and XI as it is neither used nor made by the methods of Groups V, VI, VII, VIII, X, and XI.

The antibody of Group III is unrelated to the methods of Groups VI, VII, VIII, and XI as it is neither used nor made by the methods of Groups VI, VII, VIII, and XI.

The methods of Groups V, VI, VII, VIII, X, and XI are independent as they comprise different steps and produce different results.

The pharmaceutical composition of Group IX is unrelated to the methods of Groups V, VI, VII, and XI as it is neither used nor made by the methods of Groups V, VI, VII, and XI.

Inventions II and VII or VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention II can be used in the distinct methods of Inventions VII and VIII.

Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention I has other uses, such as in gene therapy or to make the protein of Invention II.

Inventions III and V or X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention III can be used in the distinct methods of Inventions V and X.

The antibody of Group III is related to the pharmaceutical composition of Group IX by virtue of being an agent capable of binding the human enzyme related to the UDP-

glucuronosyltransferase drug-metabolizing protein subfamily of Group II. However, they are distinct inventions because the pharmaceutical composition of Group IX includes only those agents identified by the method of Group VIII which can be chemically and functionally unrelated to immunoglobulins, therefore, it does not require the antibody of Group III. Further, the antibody of Group III can be used in materially different and distinct processes such as the method of Group VI or the purification of the protein in Group II.

The pharmaceutical composition of Group IX is related to the method of Group VIII by virtue of containing an agent that can be identified with this method. However these are patentably distinct inventions because the pharmaceutical composition of Group IX may neither be made by nor used in the method of Group VIII.

Inventions IX and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Invention X can use the antibody of Invention III in a pharmaceutical composition of its own right.

Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the recombinant host cells of Invention I and native cells that normally express

the human enzyme related to the UDP-glucuronosyltransferase drug-metabolizing protein subfamily can be used in the method of Invention XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4242. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
July 30, 2001

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